**House File 729 - Introduced**

HOUSE FILE 729
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 228)

## A BILL FOR

An Act relating to pharmacy benefits managers, pharmacies, and prescription drug benefits, and including applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 505.26, subsection 1, paragraph b, Code 2021, is amended to read as follows:

*b. "Pharmacy benefits manager"* means the same as defined in section ~~510B.1~~ 510C.1.

Sec. 2. Section 507B.4, subsection 2, Code 2021, is amended by adding the following new paragraph:

NEW PARAGRAPH. *t. Pharmacy benefits managers.* Any violation of chapter 510B by a pharmacy benefits manager.

Sec. 3. Section 510B.1, Code 2021, is amended by striking the section and inserting in lieu thereof the following:

**510B.1 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *"Clean claim"* means a claim that has no defect or impropriety, including a lack of any required substantiating documentation, or other circumstances requiring special treatment, that prevents timely payment from being made on the claim.

2. *"Commissioner"* means the commissioner of insurance.

3. *"Cost-sharing"* means any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense obligation imposed by a health benefit plan on a covered person.

4. *"Covered person"* means a policyholder, subscriber, or other person participating in a health benefit plan that has a prescription drug benefit managed by a pharmacy benefits manager.

5. *"Health benefit plan"* means the same as defined in section 514J.102.

6. *"Health care professional"* means the same as defined in section 514J.102.

7. *"Health carrier"* means the same as defined in section 514J.102.

8. *"Maximum allowable cost"* means the maximum amount that a pharmacy will be reimbursed by a pharmacy benefits manager or a

health carrier for a generic drug, brand-name drug, biologic product, or other prescription drug, and that may include any of the following:

*a.* Average acquisition cost.

*b.* National average acquisition cost.

*c.* Average manufacturer price.

*d.* Average wholesale price.

*e.* Brand effective rate.

*f.* Generic effective rate.

*g.* Discount indexing.

*h.* Federal upper limits.

*i.* Wholesale acquisition cost.

*j.* Any other term used by a pharmacy benefits manager or a health carrier to establish reimbursement rates for a pharmacy.

9. *"Maximum allowable cost list"* means a list of prescription drugs that includes the maximum allowable cost for each prescription drug and that is used, directly or indirectly, by a pharmacy benefits manager.

10. *"Pharmacy"* means the same as defined in section 155A.3.

11. *"Pharmacy acquisition cost"* means the cost to a pharmacy for a prescription drug as invoiced by a wholesale distributor.

12. *"Pharmacy benefits manager"* means the same as defined in section 510C.1.

13. *"Pharmacy benefits manager affiliate"* means a pharmacy or a pharmacist that directly or indirectly through one or more intermediaries, owns or controls, is owned and controlled by, or is under common ownership or control of, a pharmacy benefits manager.

14. *"Pharmacy network"* or *"network"* means pharmacies that have contracted with a pharmacy benefits manager to dispense or sell prescription drugs to covered persons of a health benefit plan for which the pharmacy benefits manager manages the prescription drug benefit.

15. *"Prescription drug"* means the same as defined in section 155A.3.

16. "*Prescription drug benefit*" means the same as defined in section 510C.1.

17. "*Prescription drug order*" means the same as defined in section 155A.3.

18. "*Wholesale distributor*" means the same as defined in section 155A.3.

Sec. 4. Section 510B.2, Code 2021, is amended to read as follows:

**510B.2 Certification as a third-party administrator required.**

A pharmacy benefits manager doing business in this state shall obtain a certificate of registration as a third-party administrator ~~under chapter 510~~ pursuant to section 510.21, and the provisions relating to a third-party administrator pursuant to chapter 510 shall apply to a pharmacy benefits manager.

Sec. 5. Section 510B.4, Code 2021, is amended to read as follows:

**510B.4 Performance of duties — good faith — conflict of interest.**

1. A pharmacy benefits manager shall ~~perform the pharmacy benefits manager's duties exercising~~ exercise good faith and fair dealing in the performance of ~~its~~ the pharmacy benefits manager's contractual obligations toward ~~the covered entity~~ a health carrier.

2. A pharmacy benefits manager shall notify ~~the covered entity~~ a health carrier in writing of any activity, policy, practice ownership interest, or affiliation of the pharmacy benefits manager that presents any conflict of interest.

Sec. 6. Section 510B.5, Code 2021, is amended to read as follows:

**510B.5 Contacting covered ~~individual~~ persons — requirements.**

A pharmacy benefits manager, unless authorized pursuant to the terms of its contract with a ~~covered entity~~ health carrier, shall not contact any covered ~~individual~~ person without the express written permission of the ~~covered entity~~ health carrier.

Sec. 7. Section 510B.6, Code 2021, is amended to read as follows:

**510B.6 ~~Dispensing of substitute~~ Substitute prescription ~~drug for prescribed drug~~ drugs.**

1. The following provisions shall apply ~~when~~ if a pharmacy benefits manager requests the dispensing of a substitute prescription drug for a ~~prescribed~~ drug ~~to~~ prescribed for a covered ~~individual~~ person by the covered person's health care professional:

*a.* The pharmacy benefits manager may request the substitution of a lower priced generic and therapeutically equivalent prescription drug for a higher priced ~~prescribed~~ prescription drug.

*b.* If the substitute prescription drug's net cost to the covered ~~individual~~ person or ~~covered entity~~ to the health carrier exceeds the cost of the ~~prescribed~~ prescription drug originally prescribed for the covered person, the substitution shall be made only for medical reasons that benefit the covered ~~individual~~ person as determined by the covered person's prescribing health care professional.

2. A pharmacy benefits manager shall obtain the approval of the prescribing ~~practitioner~~ health care professional prior to requesting any substitution under this section.

3. A pharmacy benefits manager shall not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution.

Sec. 8. Section 510B.7, Code 2021, is amended by striking the section and inserting in lieu thereof the following:

**510B.7 Pharmacy networks.**

1. A pharmacy located in the state shall not be prohibited from participating in a pharmacy network provided that the pharmacy accepts the same terms and conditions as the pharmacy benefits manager imposes on the pharmacies in the network.

2. A pharmacy benefits manager shall not assess, charge, or collect any form of remuneration that passes from a pharmacy

or a pharmacist in a pharmacy network to the pharmacy benefits manager including but not limited to claim processing fees, performance-based fees, network participation fees, or accreditation fees.

Sec. 9. Section 510B.8, Code 2021, is amended by striking the section and inserting in lieu thereof the following:

**510B.8 Prescription drugs —— point of sale.**

1. A covered person shall not be required to make a cost-sharing payment at the point of sale for a prescription drug in an amount that exceeds the maximum allowable cost for that drug at the pharmacy at which the covered person fills the covered person's prescription drug order.

2. A pharmacy benefits manager shall not prohibit a pharmacy from disclosing the availability of a lower-cost prescription drug option to a covered person, or from selling a lower-cost prescription drug option to a covered person.

3. Any amount paid by a covered person for a prescription drug purchased pursuant to this section shall be applied to any deductible imposed by the covered person's health benefit plan in accordance with the health benefit plan coverage documents.

4. A covered person shall not be prohibited from filling a prescription drug order at any pharmacy located in the state provided that the pharmacy accepts the same terms and conditions as the pharmacy benefits manager imposes on at least one of the pharmacy networks that the pharmacy benefits manager has established in the state.

5. A pharmacy benefits manager shall not impose different cost-sharing or additional fees on a covered person based on the pharmacy at which the covered person fills the covered person's prescription drug order.

6. A pharmacy may decline to dispense a prescription drug to a covered person if, as a result of the maximum allowable cost list to which the pharmacy is subject, the pharmacy will be reimbursed less for the prescription drug than the pharmacy's acquisition cost.

Sec. 10. NEW SECTION. **510B.8A Maximum allowable cost lists.**

1. Prior to placement of a particular prescription drug on a maximum allowable cost list, a pharmacy benefits manager shall ensure that all of the following requirements are met:

*a.* The particular prescription drug must be listed as therapeutically and pharmaceutically equivalent in the most recent edition of the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", published by the United States food and drug administration, otherwise known as the orange book.

*b.* The particular prescription drug must not be obsolete or temporarily unavailable.

*c.* The particular prescription drug must be available for purchase, without limitations, by all pharmacies in the state from a national or regional wholesale distributor that is licensed in the state.

2. For each maximum allowable cost list that a pharmacy benefits manager uses in the state, the pharmacy benefits manager shall do all of the following:

*a.* Provide each pharmacy in a pharmacy network reasonable access to the maximum allowable cost list to which the pharmacy is subject.

*b.* Update the maximum allowable cost list within seven calendar days from the date of an increase of ten percent or more in the pharmacy acquisition cost of a prescription drug on the list by one or more wholesale distributors doing business in the state.

*c.* Update the maximum allowable cost list within seven calendar days from the date of a change in the methodology, or a change in the value of a variable applied in the methodology, on which the maximum allowable cost list is based.

*d.* Provide a reasonable process for each pharmacy in a pharmacy network to receive prompt notice of all changes to the maximum allowable cost list to which the pharmacy is subject.

Sec. 11. NEW SECTION. **510B.8B Pharmacy benefits manager**

**affiliates —— reimbursement.**

A pharmacy benefits manager shall not reimburse any pharmacy located in the state in an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for dispensing the same prescription drug as dispensed by the pharmacy. The reimbursement amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

Sec. 12. NEW SECTION. **510B.8C Clean claims.**

After the date of receipt of a clean claim submitted by a pharmacy in a pharmacy network, a pharmacy benefits manager shall not retroactively reduce payment on the claim, either directly or indirectly, except if the claim is found not to be a clean claim during the course of a routine audit.

Sec. 13. NEW SECTION. **510B.8D Appeals and disputes.**

1. A pharmacy benefits manager shall provide a reasonable process to allow a pharmacy to appeal a maximum allowable cost, or a reimbursement made under a maximum allowable cost list, for a specific prescription drug for any of the following reasons:

*a.* The pharmacy benefits manager violated section 510B.8A.

*b.* The maximum allowable cost is below the pharmacy acquisition cost.

2. The appeal process must include all of the following:

*a.* A dedicated telephone number at which a pharmacy may contact the pharmacy benefits manager and speak directly with an individual involved in the appeal process.

*b.* A dedicated electronic mail address or internet site for the purpose of submitting an appeal directly to the pharmacy benefits manager.

*c.* A period of at least seven business days after the date of a pharmacy's initial submission of a clean claim during which the pharmacy may initiate an appeal.

3. A pharmacy benefits manager shall respond to an appeal within seven business days after the date on which the pharmacy

benefits manager receives the appeal.

*a.* If the pharmacy benefits manager grants a pharmacy's appeal, the pharmacy benefits manager shall do all of the following:

(1) Adjust the maximum allowable cost of the prescription drug that is the subject of the appeal and provide the national drug code number that the adjustment is based on to the appealing pharmacy.

(2) Permit the appealing pharmacy to reverse and rebill the claim that is the subject of the appeal.

(3) Make the adjustment pursuant to subparagraph (1) applicable to each pharmacy in the state subject to the same maximum allowable cost list as the appealing pharmacy.

*b.* If the pharmacy benefits manager denies a pharmacy's appeal, the pharmacy benefits manager shall do all of the following:

(1) Provide the appealing pharmacy the national drug code number and the name of a wholesale distributor licensed pursuant to section 155A.17 from which the pharmacy can obtain the prescription drug at or below the maximum allowable cost.

(2) If the national drug code number provided by the pharmacy benefits manager pursuant to subparagraph (1) is not available below the pharmacy acquisition cost from the wholesale distributor from whom the pharmacy purchases the majority of its prescription drugs for resale, the pharmacy benefits manager shall adjust the maximum allowable cost list above the appealing pharmacy's pharmacy acquisition cost, and permit the pharmacy to reverse and rebill each claim affected by the pharmacy's inability to procure the prescription drug at a cost that is equal to or less than the previously appealed maximum allowable cost.

Sec. 14. Section 510B.9, Code 2021, is amended to read as follows:

**510B.9 ~~Submission, approval, and use of prior~~ Prior authorization ~~form~~.**

A pharmacy benefits manager shall ~~file with and have approved by the commissioner a single prior authorization form as provided in section 505.26~~ comply with all applicable prior authorization requirements pursuant to section 505.26. ~~A pharmacy benefits manager shall use the single prior authorization form as provided in section 505.26.~~

Sec. 15. Section 510B.10, Code 2021, is amended by striking the section and inserting in lieu thereof the following:

**510B.10 Enforcement.**

1. The commissioner shall take any enforcement action under the commissioner's authority to enforce compliance with this chapter.

2. After notice and hearing, the commissioner may impose any sanctions pursuant to section 507B.7, and may suspend or revoke a pharmacy benefits manager's certificate of registration as a third-party administrator upon a finding that the pharmacy benefits manager violated this chapter, or any applicable requirements pertaining to third-party administrators under chapter 510.

3. A pharmacy benefits manager, as an agent or vendor of a health carrier, is subject to the commissioner's authority to conduct an examination pursuant to chapter 507. The procedures set forth in chapter 507 regarding examination reports shall apply to an examination of a pharmacy benefits manager under this chapter.

4. A pharmacy benefits manager is subject to the commissioner's authority to conduct a proceeding pursuant to chapter 507B. The procedures set forth in chapter 507B regarding proceedings shall apply to a proceeding related to a pharmacy benefits manager under this chapter.

5. A pharmacy benefits manager is subject to the commissioner's authority to conduct an examination, audit, or inspection pursuant to chapter 510 for third-party administrators. The procedures set forth in chapter 510 for third-party administrators shall apply to an examination,

audit, or inspection of a pharmacy benefits manager under this chapter.

6. If the commissioner conducts an examination of a pharmacy benefits manager under chapter 507; a proceeding under chapter 507B; or an examination, audit, or inspection under chapter 510, all information received from the pharmacy benefits manager, and all notes, work papers, or other documents related to the examination, proceeding, audit, or inspection shall be confidential records pursuant to chapter 22 and shall be accorded the same confidentiality as notes, work papers, investigatory materials, or other documents related to the examination of an insurer as provided in section 507.14.

7. A violation of this chapter shall be an unfair or deceptive act or practice in the business of insurance pursuant to section 507B.4, subsection 3.

Sec. 16. NEW SECTION. **510B.11 Rules.**

The commissioner shall adopt rules pursuant to chapter 17A to administer this chapter.

Sec. 17. NEW SECTION. **510B.12 Severability.**

If a provision of this chapter or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

Sec. 18. REPEAL. Section 510B.3, Code 2021, is repealed.

Sec. 19. APPLICABILITY. This Act applies to pharmacy benefits managers that manage a health carrier's prescription drug benefit in the state on or after the effective date of this Act.

EXPLANATION

**The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.**

This bill relates to pharmacy benefits managers, pharmacies, and prescription drug benefits.

The bill requires a pharmacy benefits manager (PBM) to allow a pharmacy located in the state to participate in a pharmacy network (network) provided that the pharmacy accepts the same terms and conditions as the PBM imposes on the pharmacies in the network. "Pharmacy benefits manager" is defined in the bill as a person who, pursuant to a contract or other relationship with a health carrier, either directly or through an intermediary, manages a prescription drug benefit provided by the health carrier. "Pharmacy network", "pharmacy", "prescription drug benefit", and "health carrier" are also defined in the bill.

The bill prohibits a PBM from assessing, charging, or collecting any form of remuneration that passes from a pharmacy in the network to the PBM including but not limited to claim processing fees, performance-based fees, network participation fees, or accreditation fees.

The bill prohibits a covered person from being required to make a cost-sharing payment at the point-of-sale for a prescription drug (drug) in an amount that exceeds the maximum allowable cost (MAC) for that drug. The bill defines the "maximum allowable cost" as the maximum amount that a pharmacy will be reimbursed by a PBM or a health carrier for a generic drug, brand-name drug, biologic product, or other drug and that may include the average or national average acquisition cost; the average manufacturer price; the average wholesale price; the brand or generic effective rate; discount indexing; federal upper limits; wholesale acquisition cost; or any other term used by a PBM or health carrier to establish reimbursement rates for a pharmacy. "Covered person" is defined in the bill.

A PBM cannot prohibit a pharmacy from disclosing the availability of a lower-cost drug option to a covered person, or from selling a lower-cost drug option to a covered person. The bill requires that any amount paid by a covered person for a drug in the circumstances detailed in the bill must be applied to any deductible imposed by the covered person's

health benefit plan in accordance with the plan's coverage documents. Under the bill, a covered person cannot be prohibited from filling a drug order at any pharmacy located in the state if the pharmacy accepts the same terms and conditions as the PBM imposes on at least one of the pharmacy networks that the PBM has established in the state. A PBM cannot impose different cost-sharing or additional fees on a covered person based on the pharmacy at which a covered person fills their prescription. The bill allows a pharmacy to decline to dispense a drug to a covered person if, as a result of the maximum allowable cost list (MACL) to which the pharmacy is subject, the pharmacy will be reimbursed less than the pharmacy's acquisition cost. "Pharmacy acquisition cost" is defined in the bill. "Maximum allowable cost list" is defined in the bill as a list of prescription drugs that includes the MAC for each drug and that is used, directly or indirectly, by a PBM. "Pharmacy acquisition cost" is also defined in the bill.

The bill requires that prior to placement of a particular drug on a MACL, a PBM must ensure that the drug is listed as therapeutically and pharmaceutically equivalent in the most recent edition of the "Approved Drug Products with Therapeutic Equivalence Evaluations", published by the United States food and drug administration; the drug cannot be obsolete or temporarily unavailable; and the drug must be available for purchase by all pharmacies in the state from a national or regional wholesale distributor (distributor) that is licensed in the state. "Wholesale distributor" is defined in the bill.

The bill requires a PBM to provide each pharmacy in a network reasonable access to the MACL to which the pharmacy is subject, and to update each MACL within seven calendar days from the date of an increase of 10 percent or more in the pharmacy acquisition cost of a drug by one or more distributors doing business in the state. The PBM must also update a MACL within seven calendar days from the date of a change in the

methodology, or a change in a value of a variable applied in the methodology, on which the MACL is based. The PBM is also required to provide a process for each pharmacy in a network to receive prompt notice of all changes to a MACL.

The bill prohibits a PBM from reimbursing a pharmacy located in the state in an amount less than the amount that the PBM reimburses a PBM affiliate for dispensing the same drug as the pharmacy. "Pharmacy benefits manager affiliate" is defined in the bill.

The bill provides that after the date of receipt of a clean claim submitted by a pharmacy, a PBM cannot retroactively reduce payment on the claim, either directly or indirectly, except if the claim is found not to be a clean claim during the course of a routine audit. "Clean claim" is defined in the bill.

The bill requires a PBM to provide a process for pharmacies to appeal a MAC, or a reimbursement made under a MACL. The requirements for the appeal process are detailed in the bill.

The commissioner of insurance (commissioner) is required to take any enforcement action under the commissioner's authority to enforce compliance with the bill. After notice and hearing, the commissioner may impose any sanctions pursuant to Code section 507B.7, and may suspend or revoke a PBM's certificate of registration as a third-party administrator (administrator) upon a finding that the PBM violated any requirements of the bill, or any applicable requirements pertaining to administrators under Code chapter 510.

A PBM is subject to the commissioner's authority to conduct an examination pursuant to Code chapter 507 and a proceeding pursuant to Code chapter 507B. A PBM is also subject to the commissioner's authority to conduct an examination, audit, or inspection pursuant to Code chapter 510. If the commissioner conducts an examination, a proceeding, an audit, or an inspection, all information received from the PBM, and all documents related to the examination, proceeding, audit, or

inspection are confidential records pursuant to Code chapter 22.

A violation of the bill is an unfair or deceptive act or practice in the business of insurance pursuant to Code section 507B.4.

The bill requires the commissioner to adopt rules to administer the bill.

If a provision of the bill or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the bill that can be given effect without the invalid provision or application.

The bill make conforming changes to Code sections 510B.2, 510B.4, 510B.5, 510B.6, and 510B.9.

The bill repeals Code section 510B.3 which is replaced in large part by new Code section 510B.10 (enforcement).

The bill applies to PBMs that manage a health carrier's prescription drug benefit in the state on or after the effective date of the bill.